

## **REMARKS**

Applicants have read and considered the Office Action dated September 25, 2003 and the references cited therein. Claims 41 to 80 remain pending in the application. Reconsideration of this Application and entry of the foregoing amendments are requested.

In the Office Action, claims 41, 68, 70 and 76 were rejected under 35 U.S.C. § 102(b) as being anticipated by Tuompo *et al.* (US 5,910,420). Claims 41-80 were rejected under 35 U.S.C. § 103(a) as being obvious in view of Barbeau *et al.* (US 5,731,275) and Nishigushi *et al.* (Applied and Environmental Microbiology).

Claims 41 and 68 have been amended to delete the term "about" from the excluded compositions. Further these two claims have been amended to exclude a composition comprising 1% SDS and 0.1% or less EDTA. Additionally, the limitation "without mechanical aid" has been added to claims 41 and 68. A method for removing a biofilm from a surface without mechanical aid is now defined in the claims. Furthermore, Claim 41 has been amended to include the acid, which together with its corresponding salt, displaces divalent cations.

Claim 68 has been further amended to delete the proviso clause concerning two compositions: "of about 0.25% SDS, about 2% sodium benzoate and about 0.2% sodium salicylate, nor a mixture of about 0.1 to about 0.3% SDS or SDDD, about 0.1 to about 0.3% SCS or SLS, about 0.1% zinc sulfate, acetate, nitrate or gluconate salts and about 0.1 – 0.3% HEEDTA, EDTA or DTPA". There is no need to exclude these compositions from claim 68. These modifications render claims 77 and 78, dependent on claim 41, consistent with the scope of 68.

Claim 76 has been amended to stretch the concentration of EDTA from about 0.25% to about 1%.

Claims 43-52, 62, 63, 66, 67, 70, 72, and 74-76 have been amended in order to improve the language of these claims. More specifically, the term "about" has been deleted.

Claims 41 and 68 have been amended to delete the term "about" from the proviso clause, clarifying the scope of what is claimed. Claim 41 has been further amended to include the acid, which together with its corresponding salt and the detergent, work to displace divalent cations from the structure of the biofilm. Even though the Examiner appears to read that virtually any soap composition is embraced by the scope of the present invention, it should be emphasized that the present invention illustrates that a mixture of an acid, its corresponding salt, and a detergent is capable of dislodging a biofilm, when contacted with the latter for a time sufficient to dislodge or dismantle its structure.

The composition disclosed by Tuompo *et al.* has been expressly excluded from the scope of the claims of the present invention (1% SDS and 0.1% or less EDTA). Very low concentrations of EDTA (0.1% or less) are therefore excluded as possible salts from the present invention. These low concentrations will not sufficiently remove the biofilm within an acceptable or practical amount of time. The present claims furthermore indicate that the removal of the biofilm does not necessitate any mechanical aid. Tuompo *et al.* teach the use of a mechanical aid when they harvest a sample of microorganism; they either swab or scrub the contaminated surface. In the present invention there is no need for such mechanical aid, this is particularly emphasized in those cases where the invention is used to decontaminate small diameter water lines.

In contrast to the present application, Tuompo *et al.* are not concerned with the decontamination (*i.e.* removal of a biofilm) of a surface. Tuompo *et al.* remove a sample of the colonizing microorganisms and keep it alive in order to study it. There is no mention nor any teaching nor suggestion of decontamination. Moreover, in column 3 (lines 21-26), it is stated that "there is a need also to eliminate the disadvantages caused by the biofilms by cleaning and disinfecting the microbial growing surfaces, such as various tubing by strong disinfectants. Even strong disinfectants, however, are not necessarily able to remove the biofilms or to loosen their structures, so that the cleaning or disinfectant treatment would succeed".

In an attempt to understand the nature and the resistance of biofilms, Tuompo *et al.* have invented a method for studying and observing biofilms prior to them becoming visible. The method disclosed by Tuompo *et al.* does not decontaminate a surface from growing biofilms; it does not solve the problem of biofilms growing in small diameter water lines. Tuompo *et al.*

make use of different categories of components in their loosening compositions. The duration of the treatment is very short; 1 to 30 minutes (column 8, line 67).

Applicants have illustrated that even a very good composition comprising 1% acid/salt and 1% SDS requires about 1 hour to remove a biofilm. Applicants submit that low concentrations of components such as disclosed by Tuompo *et al.* would not be expected to remove a biofilm within 30 minutes. Applicants therefore respectfully submit that in light of the compositions disclosed, Tuompo did neither seek nor succeed in decontaminating a surface. A method by which a biofilm could be removed so as to completely decontaminate a surface therefrom is not disclosed or suggested by Tuompo *et al.*

Nishiguchi *et al.* teach the use of SDS and EDTA in solutions for extracting DNA. Applicants submit that extraction buffers usually comprise these two components to solubilize or re-suspend DNA or proteic molecules. This use, even though current in molecular biology, is very different from removing biofilms from a surface as contemplated by the present invention. Applicants respectfully submit that there would be no motivation for a person skilled in the art interested in the problem of decontaminating biofilm surfaces to read Nishiguchi's reference. Applicants did not discover that SDS solubilizes and stabilizes large molecules; they invented a solution for cleaning surfaces of established biofilms. Applicants discovered that the combination of an acid, salt and detergent constitutes an efficient combination for dismantling a biofilm. Additionally, there is no need for any mechanical stirring in order for the solutions to perform properly.

Applicants respectfully submit that the composition (SDS or SDDD + zinc salt + EDTA or DTPA or HEEDTA, and SCS or SLS), as disclosed in European Patent 0 109 279 should not be excluded from the present application. This patent is directed at disinfecting surgical material on which no biofilm has presumably had the time to establish itself. This reference is more particularly interested in the decontaminating power of hydrogen peroxide. There is no indication that this composition, without peroxide, would be efficient in removing an established biofilm, nor is there any teaching that the composition including hydrogen peroxide would be successful in removing established biofilms. It is well established that biofilms are very resistant to decontamination because of their tight structure. What is effective against planktonic or free microorganisms would not necessarily work on biofilm-organized microorganisms.

In view of the foregoing, it is believed that the rejections of the claims have been overcome by the present remarks and amendments, and that the presently claimed method is original and patentable and is in condition for allowance.

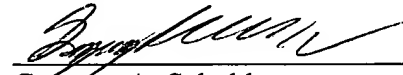
A speedy and favorable action on the merits is hereby solicited. If a telephone interview would be helpful in this matter, please contact Applicants' Representative at (612) 336-4728.

Respectfully submitted,

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